Cancel claims 2, 3, 17, 20-22, 25, 30 and 34-36 as unnecessary and without prejudice.

REMARKS

Reconsideration of this application as now amended is respectfully requested.

To advance the prosecution of this case, applicant has now amended claims 1, 8, 18, 27, 31, 32 and 37 and cancelled claims 2, 3, 17, 20-22, 25, 30 and 34-36. Two claims (38 and 39) have been added, with claims 38 and 39 being substituted for cancelled claims 25 and 34-36. That leaves a total of 15 claims in this application (specifically, claims 1, 8, 14, 18, 19, 26-29, 31-33 and 37-39), only two of which are independent claims (claims 1 and 38).

Referring to the Official action, in Section 5, pages 2-5, the Examiner again rejected most of applicant's claims for obviousness under 35 USC 103 over a combination of the Hadvary patent 4,598,089 taken in combination with six secondary references. In discussing that rejection, the Examiner also referred (on pages 3 and 4) to three newly-cited references, namely, Sterling et al 5,753,228 and the Perryman et al and Martin et al articles. Then, in Section 6, pages 5 and 6, under the heading New Grounds of Rejection, the Examiner rejected two additional claims, the

only other claims then in the application, as unpatentable under Section 103 over a combination of the same 10 references. Therefore, for purposes of this response applicant will address the patentability of all of the present claims over the teachings of all 10 references considered in combination.

It is applicant's position that someone skilled in the art at the time this invention was made would find it surprising and unobvious that avian-produced anti-lipase antibodies fed orally to a post-suckling mammal having a normally functioning (i.e., disease-free) digestive system would markedly inhibit the pancreatic lipase activity of that mammal. The reason, as set forth previously and now in a supplemental affidavit by Dr. Atkinson (submitted herewith), is that someone skilled in this field would not expect orally administered pancreatic lipase antibodies to reach the lower gastro-intestinal tract of such a mammal and still be sufficiently intact as to be capable of binding to and inhibiting the activity of the pancreatic lipase produced by that mammal. It is believed that all of the references taken in combination do not teach or suggest otherwise.

Important qualifications here are that the mammal involved be in the post-suckling stage of its development

and that its system be free of pathogenic organisms that would be disruptive of normal digestive functions. As explained in the Atkinson affidavit, it is well known that antibodies in a mother's milk are capable of traveling through the digestive tract of nursing offspring and of retaining their activity in the not-fully-developed digestive systems of such offspring. As the offspring matures, however, its digestive system advances in its ability to digest protein and, once the young mammal has past the suckling stage, and assuming its digestive system has no abnormalities and is free of disease, it would be expected that orally administered anti-lipase antibodies would not reach the lower intestine without being broken down by the digestive process itself.

It is therefore believed surprising and unexpected that avian-produced anti-lipase antibodies, when fed orally to post-suckling non-ruminant mammals as disclosed in the examples of this application, are sufficiently effective by the time they reach the lower digestive tract to inhibit the fat-hydrolyzing activity of pancreatic lipase produced by such mammals.

Someone skilled in the art might contemplate the possibilities that different types of antibodies, such as those capable of attacking disease-causing organisms, might

be administered to a mammalian subject and not be broken down in the digestive tract if the pathological condition is such that the digestive process has been rendered partially or wholly inoperative. The method of this invention is not concerned with treatment of such a pathological condition, however; it assumes that the mammalian subject has reached an advanced stage in the development of its digestive tract, and that the digestive process is normal and not disrupted. Also, as brought out in a number of applicant's claims, it is understood that the mammalian subject be a non-ruminant one because the digestive tract of a ruminant differs markedly from that of other mammals in a number of significant respects including pH levels.

Since none of the references discloses the oral administration of antibodies -- much less anti-lipase antibodies -- to control a normal digestive function in a healthy adult (or at least post-suckling) mammal, it is submitted that all of the references taken in combination fall short of that teaching. Applicant submits that combining the multiple references as the Examiner has done is inappropriate because, as set forth in the first Atkinson affidavit, a number of them fall into non-analogous fields and there is nothing in any of them to suggest how or why a skilled artisan might be motivated to

combine the references in the manner set out in the action. Applicant's further point here is that even if the references could be considered combinable, that combination would still fall considerably short of disclosing or suggesting the invention recited in applicant's claims. It is believed that despite the numerous references collected and combined by the Examiner, a prima facie case of obviousness has not been made out and, further, that any assertion of obviousness is rebutted by the Atkinson affidavits and by the teachings of the prior art itself.

None of the references refutes what applicant believes is a keystone in analyzing obviousness in this situation, namely, that antibodies fed orally to a healthy adult (or post-suckling) non-ruminating animal would be expected to be inactivated by the digestive process before reaching the lower digestive tract. The primary reference, Hadvary et al 4,598,089 does not deal with antibodies at all, and the Moloney, Flint, Ohkaru et al and JP 02150294 (Kajita et al) references all relate to procedures in which antibodies are introduced intravenously, subcutaneously, or intra-peritoneally, not orally. Coleman 5,585,098 is specifically concerned with the special case of ruminants, and Tokoro is concerned with diseases of very young (i.e., suckling) mammals whose digestive tracts are in early

stages of development. The same is true of Martin et al which discloses oral administration of monoclonal antibodies to mammals in the suckling period of post natal development.

Perryman et al and Sterling et al 5,753,228 do refer to adult subjects, but in Perryman et al the adult mammals (scid mice) are persistently infected with C. parvum which causes severe diarrhea, obviously disrupting normal operation of the animals' digestive systems. A similar observation applies to Sterling et al 5,753,228 which describes treating intestinal parasitosis caused by C. parvum in a mammal "in need thereof." While a skilled artisan reading Perryman et al and Sterling et al could conclude that parasite-reducing antibodies might survive the digestive tract of a mammal whose digestive process is disrupted because of intestinal parasitosis, that does not make it obvious that different antibodies having a specificity for a normally-produced enzyme would be able to pass through the digestive tract of a healthy adult mammal and still retain enzyme-inhibiting binding capabilities.

Three further observations might be made concerning the Sterling et al reference. First, while the specification states that adult subjects might be treated, the only examples given in the patent deal with the treatment of

newborn mammals (mice). There are no data in the patent to support a claim that the Sterling et al method would be effective treatment for adults as well as newborns. As discussed above, there is a vast difference between the two, and applicant's invention is concerned only with the treatment of post-suckling mammals.

Second, if the Sterling et al method is indeed effective in treating pathological conditions in adults, it is conceivable that the antiparasitic egg yolk antibodies would be broken down in the digestive systems of such subjects but the degradation products would still function in treatment of the disease. Such a possibility all but eliminates predictability as to what might occur if different antibodies were administered to treat a different digestive disorder, and applicant is not even concerned with the treatment of digestive diseases but rather with the inhibition of a normal digestive function.

Third, the Sterling et al reference is a good illustration of the non-predictability and non-obviousness in the treatment of one condition in relation to the treatment of another. Sterling et al are concerned with the treatment of one type of infection, a parasitic infection, by developing passive immunity, but they cite numerous references that teach that other types of

infections, at least in newborns, may also be treated by administering specific egg yolk antibodies. The Sterling et al method was nevertheless considered to be unobvious and patentable over the recognized prior art. In the present situation, the differences are far more striking because applicant is not dealing with the prevention or treatment of infection or invasion by a foreign organisms. Applicant is instead inactivating a natural enzyme, pancreatic lipase, and doing so with antibodies that would not be expected to remain intact in the digestive tract of an adult (post-suckling) non-ruminating mammal.

As stated in previous responses, the Examiner is believed to have systematically located corollaries for most of the claimed elements and used the claimed invention as a blueprint, without pointing to reasons why a skilled artisan would be motivated to combine the references in such a manner. The Court of Appeals for the Federal Circuit specifically found such a methodology is "an illogical and inappropriate process by which to determine patentability." In re Rouffet, 47 USPQ 2d 1453, 1457 (Fed. Cir. 1998) (quoting Sensonics, Inc. v. Aerosonic Corp., 38 USPQ 2d 1551,1554 (Fed. Cir. 1996). In In re Rouffet, the Court wrote that "the examiner must show reasons that the skilled artisan, confronted with the problems of the

inventor, and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." 47 USPQ 2d at 1457-58. In reversing the Board of Patent Appeals and Interferences's holding of obviousness, the Court found that reliance on the high level of skill in the art is insufficient to establish motivation to combine references, but rather, there should have been an explanation of "what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination." 47 USPQ 2d at 1458.

In view of the above, favorable reconsideration of this application and allowance of the claims as now amended are respectfully requested.

Correction of Correspondence Address

It is noted that although official communications in this application have been sent to the inventor's address, the Applicant would prefer all further communications to be sent to his attorneys of record as set forth below:

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Further, if the Examiner upon reviewing this application and applicant's response believes that a phone

discussion might be useful, she is invited to phone either of the undersigned attorneys of record at 312/456-8000.

Very respectfully,

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